US009204962B2

(12) **United States Patent**
Silvestrini

(10) **Patent No.: US 9,204,962 B2**
(45) **Date of Patent: Dec. 8, 2015**

(54) **IN SITU ADJUSTABLE OPTICAL MASK**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 71 days.

(21) Appl. No.: **13/802,340**

(22) Filed: **Mar. 13, 2013**

(65) **Prior Publication Data**

US 2014/0277432 A1 Sep. 18, 2014

(51) **Int. Cl.**

A61F 2/16	(2006.01)
A61F 2/14	(2006.01)
G02F 1/15	(2006.01)
G03C 1/73	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/1659*** (2013.01); ***A61F 2/14*** (2013.01); ***G02F 1/15*** (2013.01); ***G03C 1/733*** (2013.01)

(58) **Field of Classification Search**

USPC 623/6.17, 6.58; 351/159.61, 159.24

See application file for complete search history.

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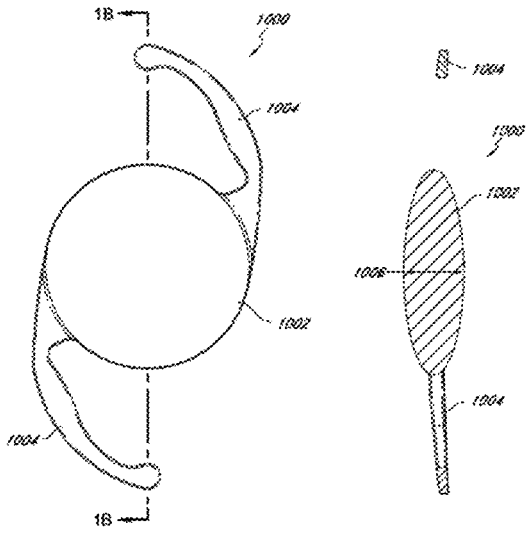
(57) **ABSTRACT**

Implantable corneal and intraocular implants such as a mask are provided. The mask can improve the vision of a patient, such as by being configured to increase the depth of focus of an eye of a patient. The mask can include an aperture configured to transmit along an optical axis substantially all visible incident light. The mask can further include a transition portion that surrounds at least a portion of the aperture. This portion can be configured to switch from one level of opacity to another level of opacity through the use of a controllably variable absorbance feature such as a switchable photochromic chromophore within a polymer matrix.

21 Claims, 12 Drawing Sheets



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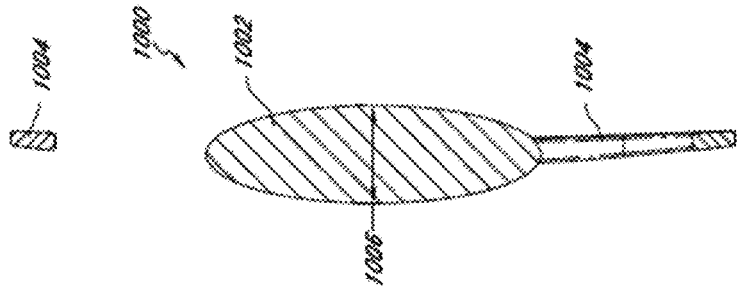

FIG. 1B

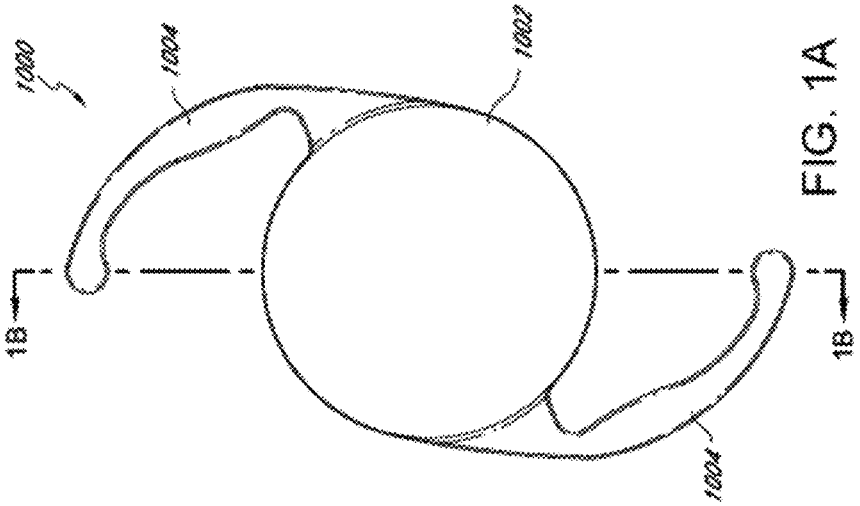

FIG. 1A

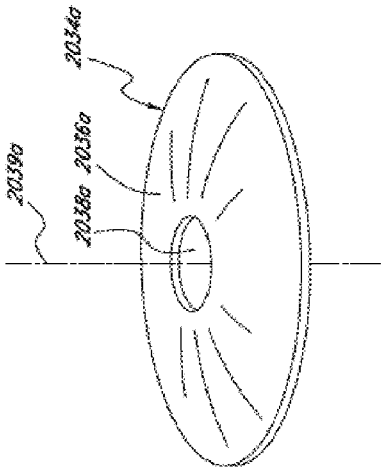

FIG. 2A

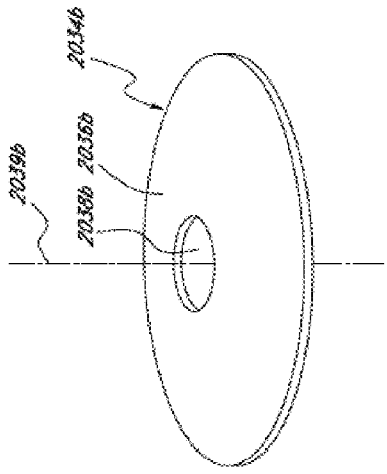

FIG. 2B

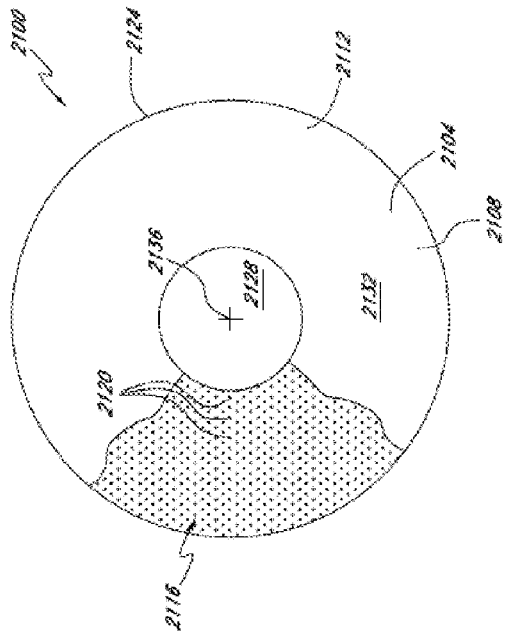

FIG. 3A

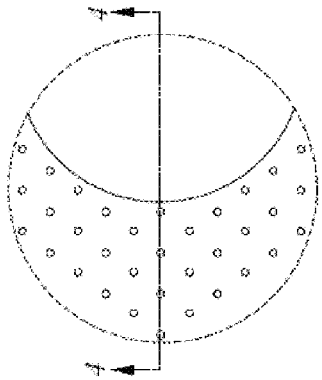

FIG. 3B

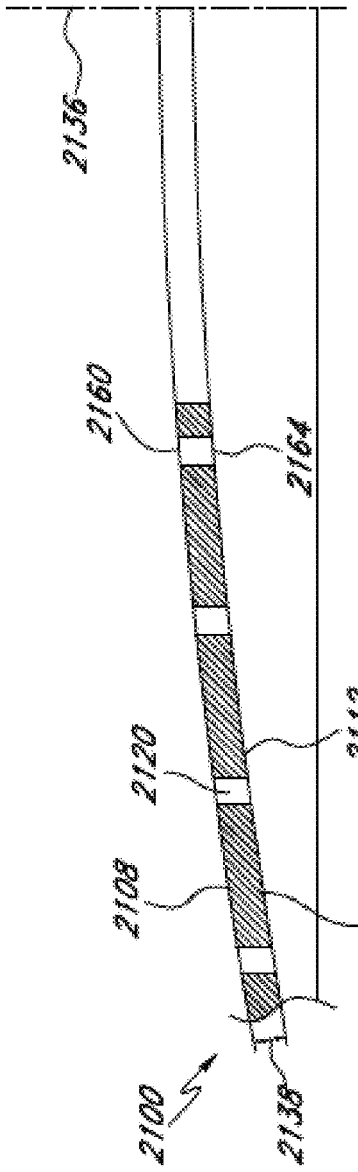

FIG. 4

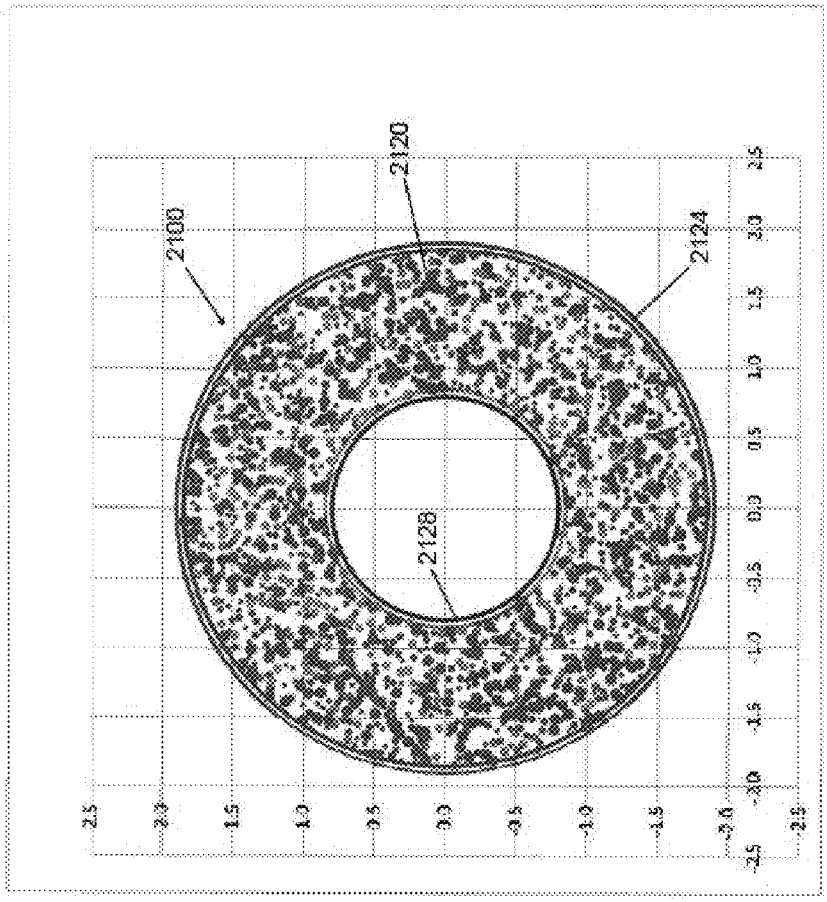

FIG. 5

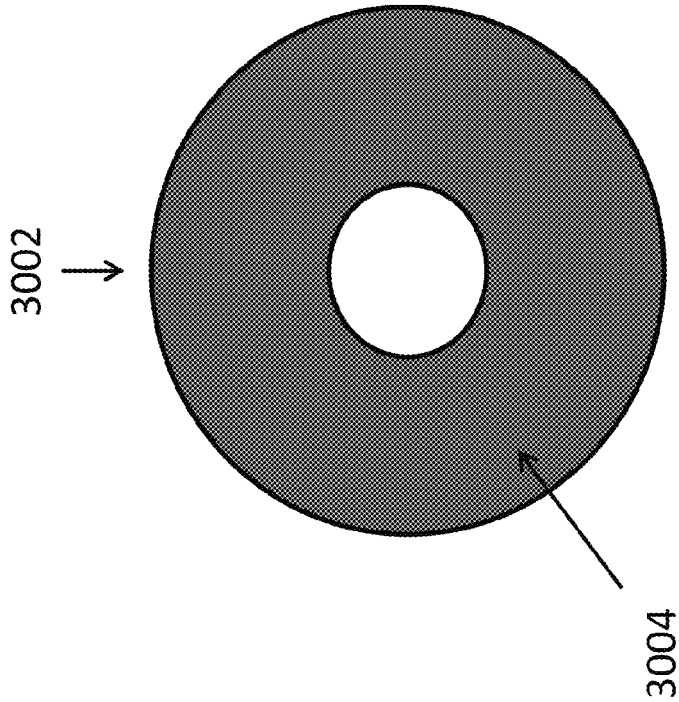

FIG. 6b

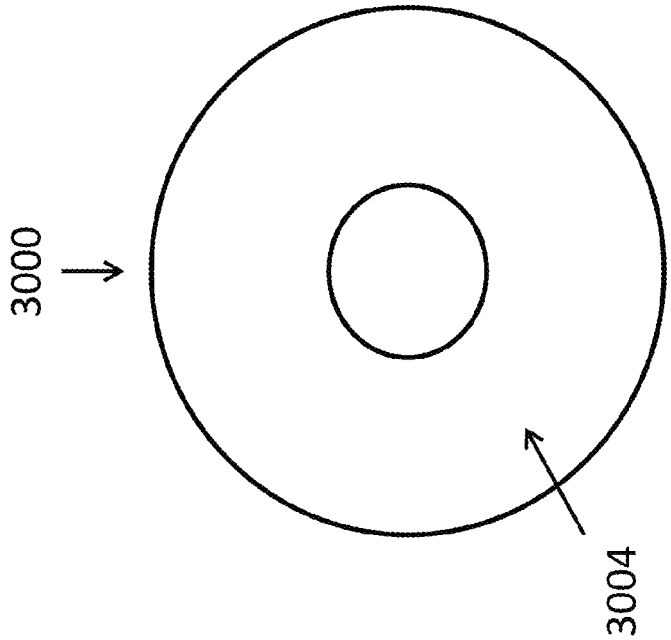

FIG. 6a

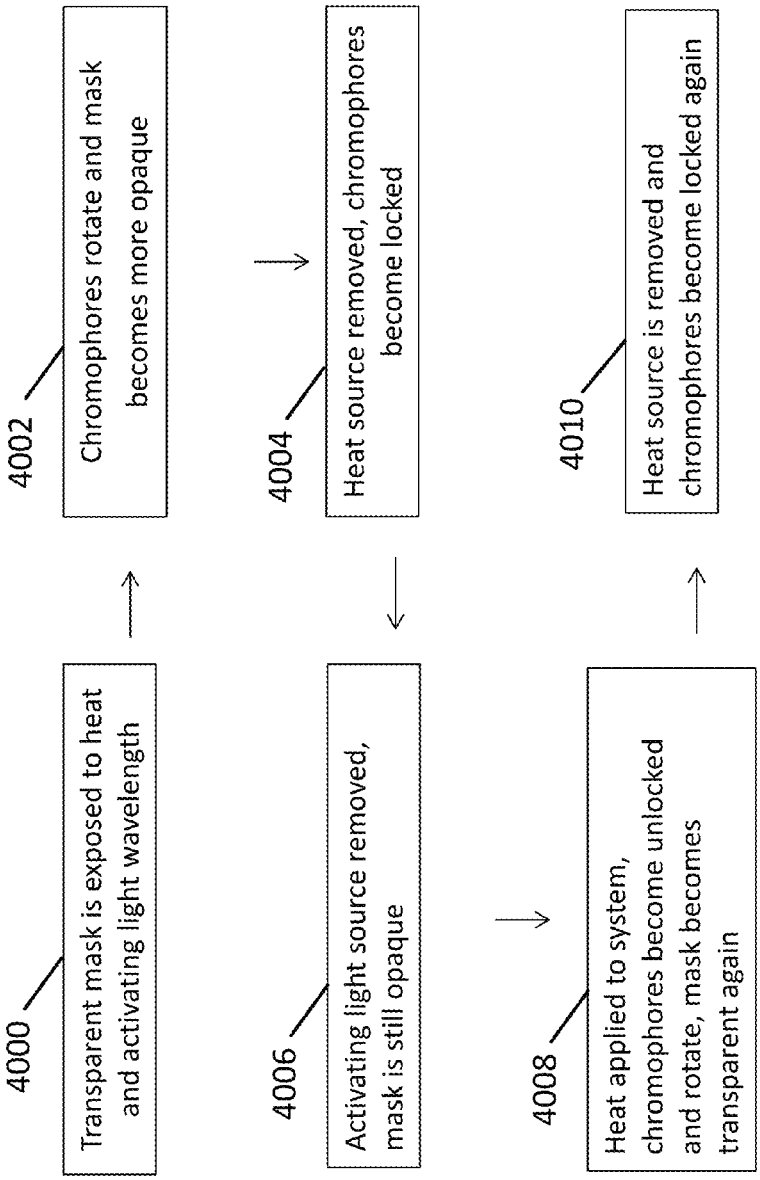
4000
Transparent mask is exposed to heat and activating light wavelength
4002
Chromophores rotate and mask becomes more opaque
4004
Heat source removed, chromophores become locked
4006
Activating light source removed, mask is still opaque
4008
Heat applied to system, chromophores become unlocked and rotate, mask becomes transparent again
4010
Heat source is removed and chromophores become locked again

FIG. 7

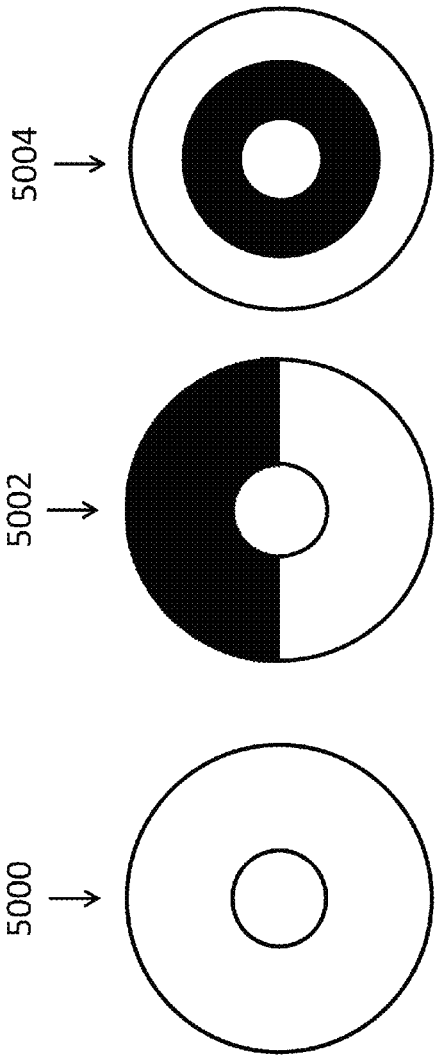

FIG. 8A

FIG. 8B

FIG. 8C

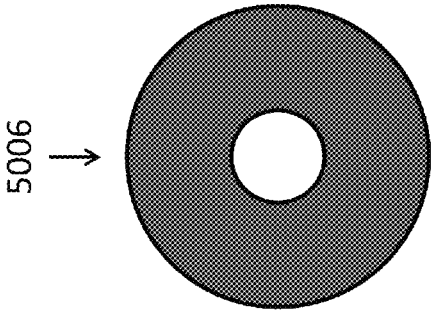

FIG. 8D

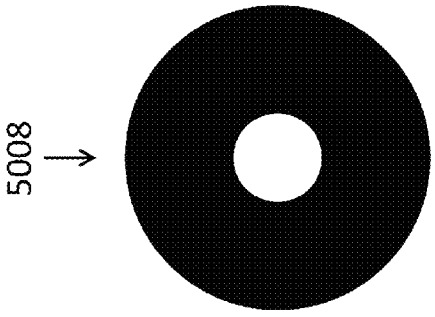

FIG. 8E

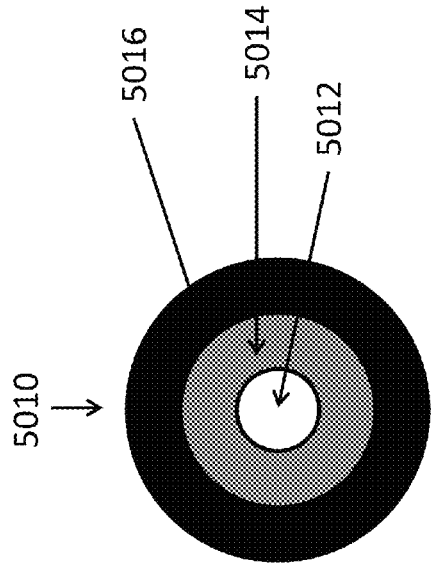

FIG. 8F

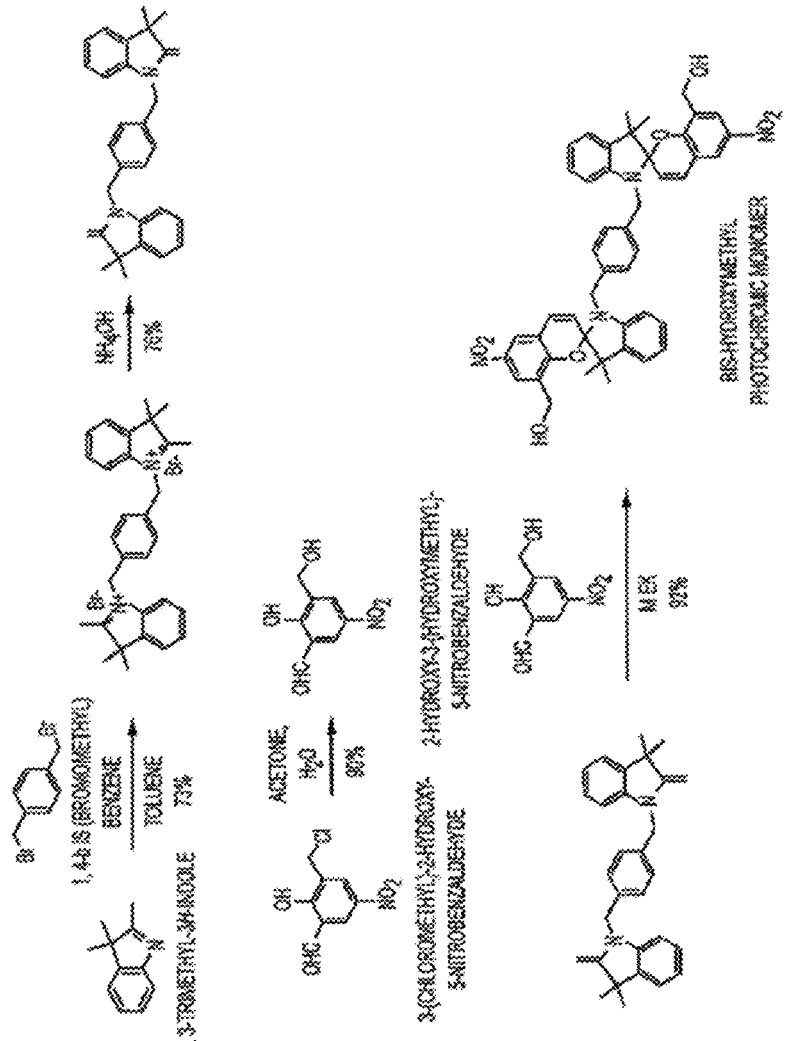
1,4-di-(BROMOMETHYL)
BENZENE
TOLUENE
77%
2,3,3-TRIMETHYL-3H-INDOLE
NH4OH
82%
ACETONE,
H2O
90%
5-(CHLOROMETHYL)-2-HYDROXY-
3-NITROBENZALDEHYDE
2-HYDROXY-3-(HYDROXYMETHYL)-
5-NITROBENZALDEHYDE
MEK
90%
BIS-HYDROXYMETHYL
PHOTOCHROMIC MONOMER

FIG. 9

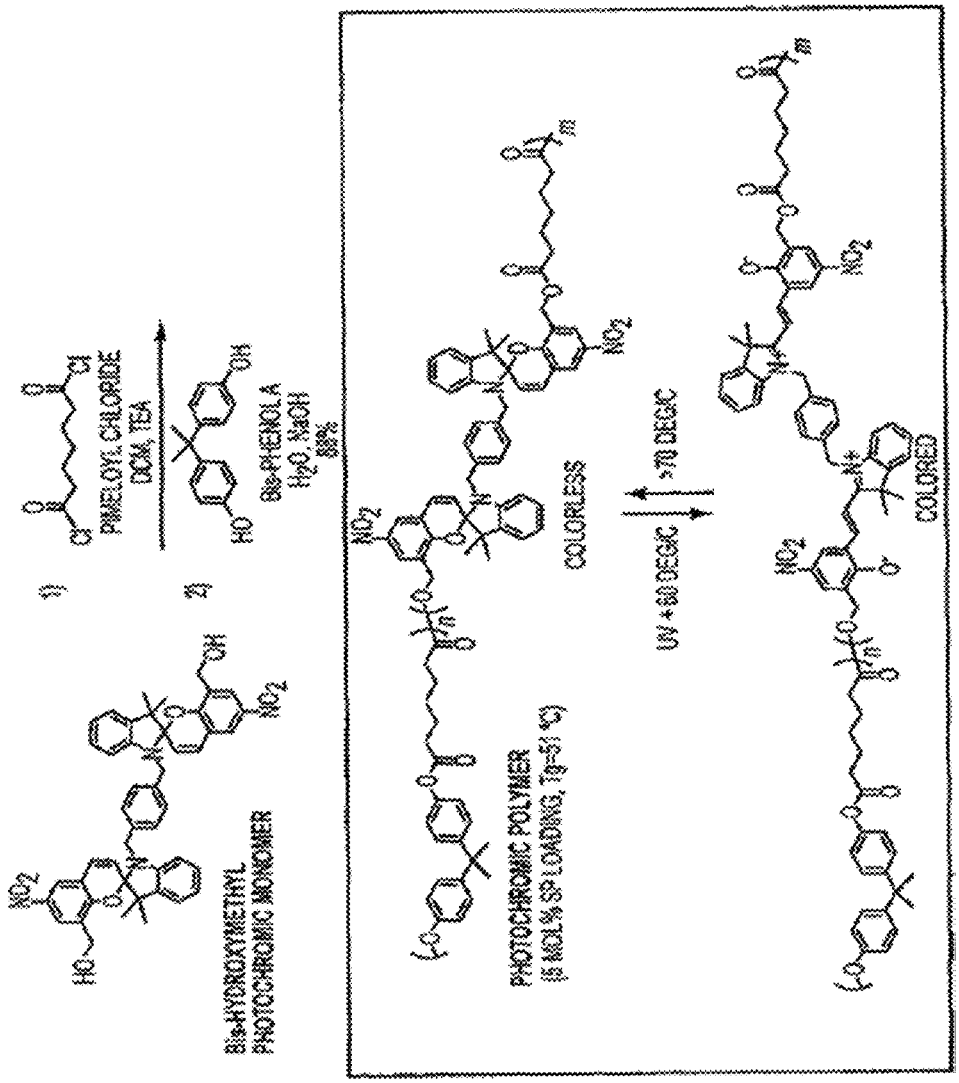
PIMELOYL CHLORIDE
DCM, TEA
Bis-PHENOL A
H2O, NaOH
88%
Bis-HYDROXYMETHYL
PHOTOCHROMIC MONOMER
PHOTOCHROMIC POLYMER
(8 MOL% SP LOADING, Tg=51 °C)
COLORLESS
UV + 60 DEGC
>70 DEGC
COLORED

FIG. 10

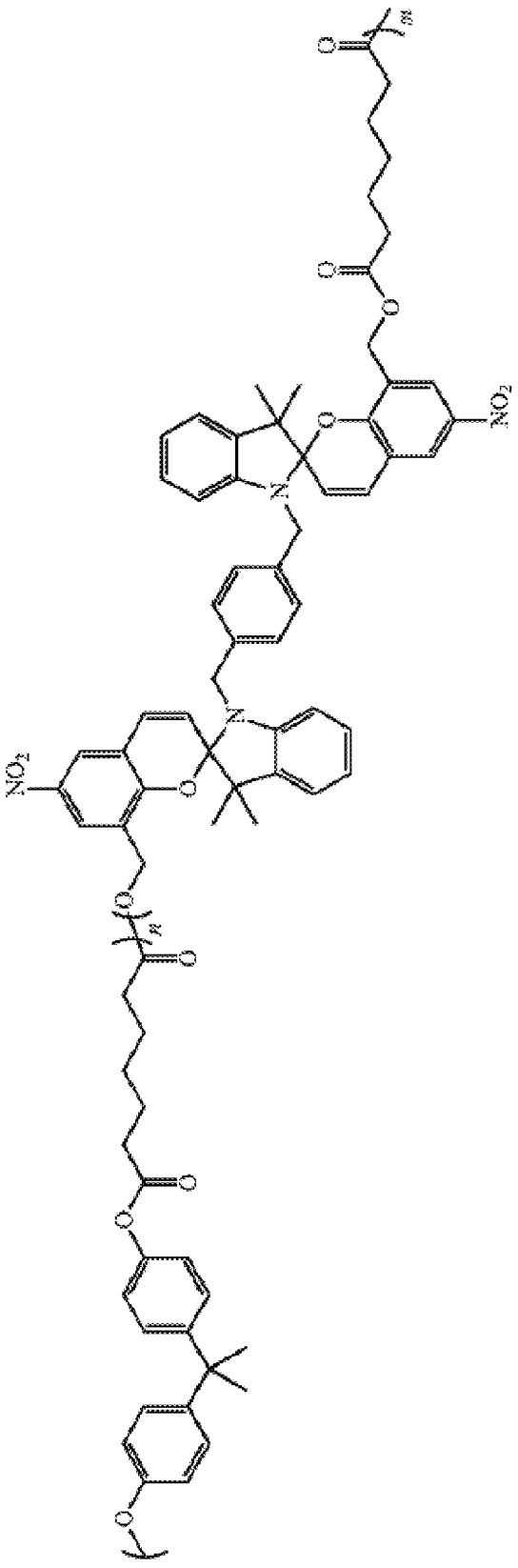

FIG. 11

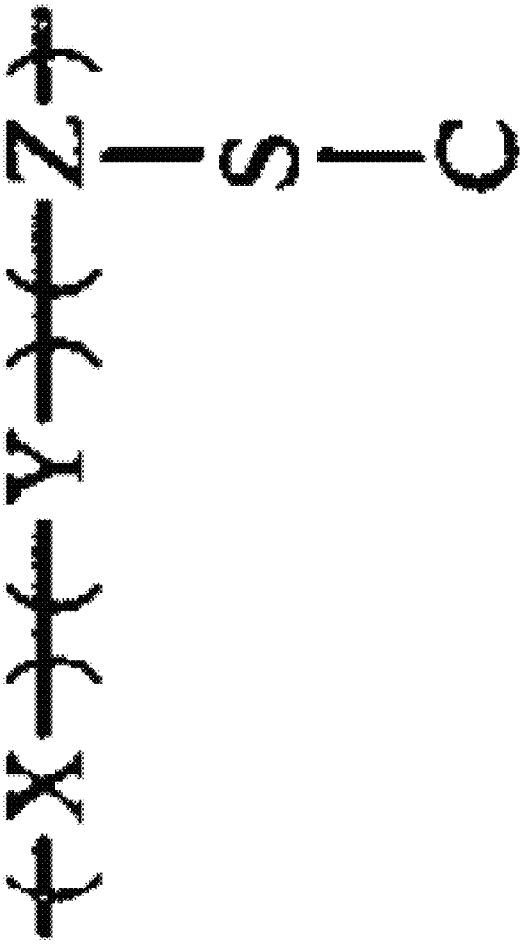

FIG. 12

IN SITU ADJUSTABLE OPTICAL MASK

BACKGROUND OF THE INVENTION

1. Field

This application relates generally to the field of ophthalmic devices. More particularly, this application is directed to corneal masks and intraocular implants, and methods of making the same.

2. Description of the Related Art

The human eye functions to provide vision by transmitting and focusing light through a clear outer portion called the cornea, and further refining the focus of the image onto a retina by way of a crystalline lens. The quality of the focused image depends on many factors including the size and shape of the eye, and the transparency of the cornea and the lens.

The optical power of the eye is determined by the optical power of the cornea and the crystalline lens. In a normal, healthy eye, sharp images of distant objects are formed on the retina (emmetropia). In many eyes, images of distant objects are either formed in front of the retina because the eye is abnormally long or the cornea is abnormally steep (myopia), or formed in back of the retina because the eye is abnormally short or the cornea is abnormally flat (hyperopia). The cornea also can be asymmetric or toric, resulting in an uncompensated cylindrical refractive error referred to as corneal astigmatism.

A normally functioning human eye is capable of selectively focusing on either near or far objects through a process known as accommodation. Accommodation is achieved by inducing deformation in a lens located inside the eye, which is referred to as the crystalline lens. Such deformation is induced by muscles called ciliary muscles. In most individuals, the ability to accommodate diminishes with age and these individuals cannot see up close without vision correction. If far vision also is deficient, such individuals are usually prescribed bifocal lenses.

SUMMARY OF THE INVENTION

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the invention have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

A first aspect of this application is directed toward an ophthalmic device comprising a mask configured to transmit substantially all visible light along an optical axis of the eye, the mask further comprising a transition portion configured to switch between at least a first degree of opacity and a second degree of opacity; and wherein the transition portion comprises a photochromic chromophore within a polymer matrix.

The mask may include an aperture configured to transmit substantially all visible light along the optical axis of the eye.

The mask may include a plurality of holes extending at least partially between an anterior surface of the mask and a posterior surface of the mask.

An intraocular lens may be coupled with the mask.

The first degree of opacity may allow transmission of substantially all visible light through the transition portion of the mask.

The second degree of opacity may prevent transmission of substantially all visible light through the transition portion of the mask.

The transition portion of the mask may comprise at least 50% of the total mask.

The transition portion may be configured to switch between a first degree of opacity and a second degree of opacity via application of both light and heat.

The polymer matrix may have a glass transition temperature of between 30-150° C.

The photochromic chromophore may comprise spiropyran.

Another aspect of this application is directed toward a method of switching the opacity of at least a portion of an ophthalmic device. The method includes providing a photochromic polymer mask with a controlled glass transition temperature, inserting the mask into an eye, and applying light and heat to the mask.

The heat may be applied via a laser, via ultrasonic energy or other energy modality for elevating the temperature of the mask.

A microscope can be used to monitor the photochromic polymer mask.

The glass transition temperature may be controlled by altering the chain length of the polymer.

The glass transition temperature may be controlled by altering the cross-link density of the polymer.

Another aspect of this application is directed toward a method of forming a mask portion. The mask includes a transition portion configured to switch between a first degree of opacity and a second degree of opacity and an aperture in the mask portion, the aperture configured to transmit substantially all visible light along an optical axis of an eye.

The method may include forming a plurality of holes in the mask portion, the plurality of holes extending at least partially between an anterior surface and a posterior surface of the mask.

The method may include coupling the mask portion with an intraocular lens.

The transition portion may include a photochromic chromophore contained within a polymer matrix.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments will be described hereinafter with reference to the accompanying drawings. These embodiments are illustrated and described by example only, and are not intended to limit the scope of the disclosure. In the drawings, similar elements have similar reference numerals.

FIGS. **1**A and **1**B depict a conventional intraocular lens.

FIG. **2**A is a perspective view of one embodiment of a mask.

FIG. **2**B is a perspective view of another embodiment of a mask.

FIG. **3**A depicts a top view of another embodiment of a mask configured to increase depth of focus.

FIG. **3**B depicts an enlarged view of a portion of the view of **3**B.

FIG. **4** is a cross-sectional view of the mask of FIG. **3**B taken along the section plane **4**-**4**.

FIG. **5** is a graphical representation of one arrangement of holes of a plurality of holes that can be formed in an ophthalmic device.

FIGS. **6**A and **6**B depict an embodiment of a mask that switches between one level of opacity and another level of opacity.

FIG. **7** is a flowchart that depicts one embodiment of a method for switching the opacity of a transition portion of a mask.

FIGS. **8**A-**8**F depict multiple embodiments of various geometries of the transition portions of a mask.

FIG. **9** depicts one embodiment of the synthesis of a photochromic monomer.

FIG. **10** depicts one embodiment of the synthesis of a photochromic polymer from the monomer of FIG. **9**.

FIG. **11** depicts one embodiment of a general formula for a photochromic polymer.

FIG. **12** depicts one embodiment of a side-chain crystallizable polymer.

DETAILED DESCRIPTION

This application is directed to ocular devices and implants (e.g., masks) for improving the depth of focus of an eye of a patient and methods and apparatuses for making such ocular devices. The masks generally employ small-aperture vision correction methods to enhance depth of focus in a presbyopic eye thereby providing functional near vision. The masks can be applied to the eye in any manner and in any anterior-posterior location along the optical path, e.g., as an implant in the cornea (sometimes referred to as a "corneal inlay"). The masks can also be embodied in or combined with lenses and applied in other regions of the eye, e.g., as or in combination with contact lenses or intraocular lenses (IOL).

The ocular devices and masks described herein can be applied to masks and/or combined with features described in U.S. Patent Publication No. 2011/0040376, filed Aug. 13, 2010, entitled "MASKED INTRAOCULAR IMPLANTS AND LENSES," and International Patent Publication No. WO 2011/020074, filed Aug. 13, 2010, entitled "CORNEAL INLAY WITH NUTRIENT TRANSPORT STRUCTURES, hereby incorporated by reference in their entirety."

A conventional intraocular lens **1000** is illustrated in FIGS. **1**A-B. The cross-sectional thickness of the lens body **1002** is generally dependent on the optical power of the intraocular lens **1000** and the material of the lens body **1002**. In particular, the central region of the lens body **1002** is generally the thickest section of the intraocular lens **1000** with a central region cross-sectional thickness **1006**. Methods for reducing the thickness of the intraocular lens are described in U.S. Pub. No. 2011/0040376, filed Aug. 13, 2010, hereby incorporated by reference in its entirety.

The intraocular lens and/or the lens body can be made from one or more materials. In certain embodiments, the intraocular lens and/or the lens body can comprise polymers (e.g. PMMA, PVDF, polypropylene, polycarbonate, PEEK, polyethylene, acrylic copolymers, polystyrene, PVC, polysulfone), hydrogels, and silicone).

A variety of variations of masks that can be used alone or positioned on or within the implant body are discussed herein, and also described in U.S. Pat. No. 7,628,810, U.S. Patent Publication No. 2006/0113054, and U.S. Patent Publication No. 2006/0265058, all of which are hereby incorporated by reference in their entirety. FIG. **2**A illustrates one embodiment of a mask **2034***a*. The mask **2034***a* can include an annular region **2036***a* surrounding an aperture **2038***a* substantially centrally located on the mask **2034***a*. The aperture **2038***a* can be generally located around a central axis **2039***a*, referred to herein as the optical axis of the mask **2034***a*. The aperture **2038***a* can be in the shape of a circle. FIG. **2**B illustrates another embodiment of a mask **2034***b* similar to the mask **2034***a* illustrated in FIG. **2**A. The annular region **2036***a* of the mask **2034***a* of FIG. **2**A has a curvature from the outer periphery to the inner periphery of the annular region **2036***a*, such that the annular region **2036***a* substantially conforms to the surface of a geometry of rotation, such as a sphere. The annular region **2036***b* of the mask **2034***b* of FIG. **2**B is substantially flat.

The mask can have a constant thickness. However, in some embodiments, the thickness of the mask can vary between the inner periphery (near the aperture **2038***a,b*) and the outer periphery.

The mask can have dimensions configured to improve a patient's vision. For example, if the mask is embedded within the implant body, the thickness of the mask can vary depending on the location of the mask relative to the implant body. For example, the mask can have a thickness greater than zero and less than the thickness of the implant body. Alternatively, if the mask is coupled to a surface of the implant body, the mask can preferably have a thickness no greater than necessary to have desired opacity so that the mask does not add additional thickness to the intraocular lens. In certain embodiments, the mask has a thickness of greater than zero and less than about 0.5 mm. In some embodiments, the mask has a thickness of at least about 0.25 mm and/or less than or equal to about 0.3 mm. In some embodiments, the mask has a thickness of at least 0.005 mm and/or less than or equal to about 0.015 mm. In one embodiment, the mask has a thickness of about 0.25 mm. If the mask is on or near the surface of a transition zone, as described in U.S. Pub. No. 2011/0040376, filed Aug. 13, 2010 and hereby incorporated by reference in its entirety, the mask can have a shape similar or the same as the transition zone.

The annular region **2036***a,b* can be at least partially opaque or can be completely opaque to visible light. The degree of opacity of the annular region **2036***a,b* prevents at least some or substantially all light from being transmitted through the mask **2034***a,b*. Generally, transmission of light through the annular region will be no more than about 5%, often no more than about 3% and in some applications, no more than about 1%. Opacity of the annular region **2036***a,b* can be achieved in any of several different ways.

For example, in one embodiment, the material used to make mask **2034***a,b* can be naturally opaque. Alternatively, the material used to make the mask **2034***a,b* can be substantially clear, but treated with a dye or other pigmentation agent to render region **2036** substantially or completely opaque. In still another example, the surface of the mask **2034** can be treated physically or chemically (such as by etching) to alter the refractive and transmissive properties of the mask **2034***a,b* and make it less transmissive to light.

The material of the mask **2034***a,b* can be, for example, any of a variety of polymeric materials. Where the mask **2034***a,b* is applied to or fixed within the intraocular implant, the material of the mask **2034** should be biocompatible. Examples of suitable materials for the mask **2034** *a,b* include the preferred PVDF, other suitable polymers or co-polymers, such as hydrogels, or fibrous materials, such as a Dacron mesh.

In additional embodiments, a photochromic material can be used as the mask or as a variable transmission zone in addition to a non-photochromic or non-variable transmission zone of the mask. Under bright light conditions, the photochromic material can darken thereby creating a mask (having a transmission aperture) and enhancing near vision. Under dim light conditions, the photochromic material lightens, which allows more light to pass through to the retina. In certain embodiments, under dim light conditions, the photochromic material lightens to expose an optic of the intraocular implant. Further photochromic material details are disclosed

in U.S. patent application Ser. No. 13/691,625, filed Nov. 30, 2012, which is hereby incorporated by reference in its entirety.

The mask can have different degrees of opacity. For example, the mask can block substantially all of visible light or can block a portion of visible light. The opacity of the mask can also vary in different regions of the mask. In certain embodiments, the opacity of the outer edge and/or the inner edge of the mask is less than the central region of the mask. The opacity in different regions can transition abruptly or have a gradient transition. Additional examples of opacity transitions can be found in U.S. Pat. Nos. 5,662,706, 5,905,561 and 5,965,330, all of which are hereby incorporated by reference in their entirety.

Further mask details are disclosed in U.S. Pat. No. 4,976,732, issued Dec. 11, 1990, U.S. Pat. No. 7,628,810, issued Dec. 8, 2009, and in U.S. patent application Ser. No. 10/854,032, filed May 26, 2004, all of which are hereby incorporated by reference in their entirety.

An advantage to embodiments that include a mask with an aperture (e.g., pin-hole aperture) described herein over multifocal IOLs, contact lenses, or refractive treatments of the cornea is that all of these latter approaches divide the available light coming through the aperture into two or more foci while a mask approach has a single focus (monofocal). This limitation forces designers of multifocal optics to choose how much of the light is directed to each focal point, and to deal with the effects of the unfocused light that is always present in any image. In order to maximize acuity at the important distances of infinity (>6M) and 40 cm (normal reading distance), it is typical to provide little or no light focused at an intermediate distance, and as a result, visual acuity at these distances is poor. With a mask that includes an aperture to increase depth-of-focus, however, the intermediate vision of presbyopic patients is improved significantly. Indeed, the defocus blur with the aperture is less at intermediate distances than at near.

FIGS. **3-4** show another embodiment of a mask **2100** configured to increase depth of focus of an eye of a patient with presbyopia. The mask **2100** is similar to the masks hereinbefore described, except as described differently below. The mask **2100** can be made of the materials discussed herein, including those discussed above. In addition, the mask **2100** can be formed by any suitable process. The mask **2100** is configured to be applied to an IOL.

In one embodiment, the mask **2100** includes a body **2104** that has an anterior surface **2108** and a posterior surface **2112**. The body **2104** can be formed of any suitable material, including at least one of an open cell foam material, an expanded solid material, and a substantially opaque material. In one embodiment, the material used to form the body **2104** has relatively high water content. In other embodiments, the materials that can be used to form the body **2104** include polymers (e.g. PMMA, PVDF, polypropylene, polycarbonate, PEEK, polyethylene, acrylic copolymers (e.g., hydrophobic or hydrophilic), polystyrene, PVC, polysulfone), hydrogels, silicone, metals, metal alloys, or carbon (e.g., graphene, pure carbon).

In one embodiment, the mask **2100** includes a hole arrangement **2116**. The hole arrangement **2116** can comprise a plurality of holes **2120**. The holes **2120** are shown on only a portion of the mask **2100**, but the holes **2120** preferably are located throughout the body **2104** in one embodiment. The mask **2100** has an outer periphery **2124** that defines an outer edge of the body **2104**. In some embodiments, the mask **2100** includes an aperture **2128** at least partially surrounded by the outer periphery **2124** and a non-transmissive or reduced transmissive portion **2132** located between the outer periphery **2124** and the aperture **2128**.

Preferably the mask **2100** is symmetrical, e.g., rotationally symmetrical about a mask axis **2136**. In one embodiment, the outer periphery **2124** of the mask **2100** is circular. The mask in general has an outer diameter of at least about 3 mm and/or less than about 6 mm. In some embodiments, the mask is circular and has a diameter of at least about 3 mm and/or less than or equal to about 4 mm. In some embodiments, the mask **2100** is circular and has a diameter of about 3.2 mm. In some embodiments, masks that are asymmetrical or that are not symmetrical about a mask axis provide benefits, such as enabling a mask to be located or maintained in a selected position with respect to the anatomy of the eye.

The body **2104** of the mask **2100** can be configured to be coupled with a particular intraocular lens design, either of reduced thickness design or of conventional design. For example, where the mask **2100** is to be coupled with a particular IOL that has curvature, the body **2104** can be provided with a corresponding amount of curvature along the mask axis **2136** that corresponds to the curvature. Likewise, the body **2104** can be provided with corresponding shape to accommodate IOL transition zones. Further details about the reduced thickness design are described in U.S. Pub. No. 2011/0040376, filed Aug. 13, 2010 and hereby incorporated by reference in its entirety.

In one embodiment, one of the anterior surface **2108** and the posterior surface **2112** of the body **2104** is substantially planar. In one planar embodiment, very little or no uniform curvature can be measured across the planar surface. In another embodiment, both of the anterior and posterior surfaces **2108**, **2112** are substantially planar. In general, the thickness of the body **2104** of the mask **2100** can be within the range of from greater than zero to about 0.5 mm, about 1 micron to about 40 microns, and often in the range of from about 5 microns to about 20 microns. In some embodiments, the body **2104** of the mask **2100** has a thickness **2138** of at least about 5 microns and/or less than or equal to about 20 microns. In some embodiments, the body **2104** of the mask has a thickness **2138** of at least about 10 microns and/or less than or equal to about 15 microns. In certain embodiments, the thickness **2138** is about 15 microns. In certain embodiments, the thickness **2138** is about 10 microns. In certain embodiments, the thickness **2138** of the mask **2100** is about 5 microns. In another embodiment, the thickness **2138** of the mask **2100** is about 8 microns. In another embodiment, the thickness **2138** of the mask **2100** is about 10 microns.

A substantially planar mask has several advantages over a non-planar mask. For example, a substantially planar mask can be fabricated more easily than one that has to be formed to a particular curvature. In particular, the process steps involved in inducing curvature in the mask **2100** can be eliminated.

The aperture **2128** is configured to transmit substantially all incident light along the mask axis **2136**. The non-transmissive portion **2132** surrounds at least a portion of the aperture **2128** and substantially prevents transmission of incident light thereon. As discussed in connection with the above masks, the aperture **2128** can be a through-hole in the body **2104** or a substantially light transmissive (e.g., transparent) portion thereof. The aperture **2128** of the mask **2100** generally is defined within the outer periphery **2124** of the mask **2100**. The aperture **2128** can take any of suitable configurations, such as those described above.

In one embodiment, the aperture **2128** is substantially circular and is substantially centered in the mask **2100**. The size of the aperture **2128** can be any size that is effective to

increase the depth of focus of an eye of a patient with presbyopia. In particular, the size of the aperture **2128** is dependent on the location of the mask within the eye (e.g., distance from the retina). In some embodiments, the aperture **2128** can have a diameter of at least about 0.85 mm and/or less than or equal to about 2.2 mm. In certain embodiments, the diameter of the aperture **2128** is less than about 2 mm. In some embodiments, the diameter of the aperture is at least about 1.1 mm and/or less than or equal to about 1.6 mm. In a further embodiment, the diameter of the aperture is at least about 1.3 mm and/or less than or equal to about 1.4 mm.

In certain embodiments, the aperture **2128** includes an optical power and/or refractive properties. For example, the aperture **2128** can include an optic and can have an optical power (e.g. positive or negative optical power). In certain embodiments, the aperture **2128** can add to the active correction of the intraocular lens.

The non-transmissive portion **2132** is configured to prevent transmission of visible light through the mask **2100**. For example, in one embodiment, the non-transmissive portion **2132** prevents transmission of substantially all of at least a portion of the spectrum of the incident visible light. In one embodiment, the non-transmissive portion **2132** is configured to prevent transmission of substantially all visible light, e.g., radiant energy in the electromagnetic spectrum that is visible to the human eye. The non-transmissive portion **2132** can substantially prevent transmission of radiant energy outside the range visible to humans in some embodiments.

As discussed above, preventing transmission of light through the non-transmissive portion **2132** decreases the amount of light that reaches the retina and the fovea that would not converge at the retina and fovea to form a sharp image. As discussed above, the size of the aperture **2128** is such that the light transmitted therethrough generally converges at the retina or fovea. Accordingly, a much sharper image is presented to the retina than would otherwise be the case without the mask **2100**.

In one embodiment, the non-transmissive portion **2132** prevents transmission of at least about 90 percent of incident light. In another embodiment, the non-transmissive portion **2132** prevents transmission of at least about 95 percent of all incident light. The non-transmissive portion **2132** of the mask **2100** can be configured to be substantially opaque to prevent the transmission of light.

In some embodiments, the non-transmissive portion **2132** can transmit no more than about 5% of incident visible light. In some embodiments, the non-transmissive portion **2132** can transmit no more than about 3% of incident visible light. In some embodiments, the non-transmissive portion **2132** can transmit no more than about 2% of incident visible light. In one embodiment, at least a portion of the body **2104** is configured to be opaque to more than 99 percent of the light incident thereon.

As discussed above, the non-transmissive portion **2132** can be configured to prevent transmission of light without absorbing the incident light. For example, the mask **2100** could be made reflective or could be made to interact with the light in a more complex manner, as discussed in U.S. Pat. No. 6,554,424, issued Apr. 29, 2003, which is hereby incorporated by reference in its entirety.

As discussed above, the mask **2100** can include a plurality of holes **2120**. The lens body can extend at least partially through the holes, thereby creating a bond (e.g. material "bridge") between the lens body on either side of the mask.

The holes **2120** of the mask **2100** shown in FIG. **3**A can be located anywhere on the mask **2100**. In some embodiments, substantially all of the holes are in one or more regions of a mask. The holes **2120** of FIG. **3**A extend at least partially between the anterior surface **2108** and the posterior surface **2112** of the mask **2100**. In one embodiment, each of the holes **2120** includes a hole entrance **2160** and a hole exit **2164**. The hole entrance **2160** is located adjacent to the anterior surface **2108** of the mask **2100**. The hole exit **2164** is located adjacent to the posterior surface **2112** of the mask **2100**. In one embodiment, each of the holes **2120** extends the entire distance between the anterior surface **2108** and the posterior surface **2112** of the mask **2100**. Further details about possible hole patterns are described in WO 2011/020074, filed Aug. 13, 2010, incorporated by reference above.

In some embodiments, the mask **2100** can include an annular region near the outer periphery **2124** of the mask having no holes. In certain embodiments, there are no holes within 0.1 mm of the outer periphery **2124** of the mask **2100**.

In some embodiments, the mask can include an annular region around the inner periphery of the mask having no holes. In certain embodiments, there are no holes within 0.1 mm of the aperture **2128**.

As shown in FIG. **5**, the mask **2100** can include a plurality of holes **2120**. In some embodiments, the holes **2120** each have a same diameter. In certain embodiments, the holes **2120** can include one or more different diameters. In some embodiments, the diameter of any single hole **2120** is at least about 0.01 mm and/or less than or equal to about 0.02 mm. In some embodiments, the diameter of the holes **2120** can include one or more of the following hole diameters: 0.010 mm, 0.013 mm, 0.016 mm, and/or 0.019 mm.

In some embodiments, the holes are interspersed at irregular locations throughout at least a portion of the mask **2100**. In some embodiments, holes of different diameters are evenly interspersed throughout at least a portion of the mask **2100**. For example, the mask **2100** can include a plurality of non-overlapping hole regions. The sum of the surface area of the plurality of non-overlapping hole regions can equal to total surface area of the entire hole region of the mask. Each region of the plurality of regions can include a number of holes, each of the holes having a different diameter. The number of holes in each region can equal the number of different hole sizes in the entire hole region.

In some embodiments, there are at least about 1000 holes and/or less than or equal to about 2000 holes. In some embodiments, there are at least about 1000 holes and/or less than or equal to about 1100 holes. In some embodiments, there are about 1040 holes. In some embodiments, there are an equal number of holes of each diameter. In some embodiments, the number of holes having each diameter is different.

FIG. **6**A-**6**B depicts one embodiment of a switchable mask where at least a portion of the mask, hereby referred to as the transition portion, is configured to switch between different levels of opacity to allow different amounts of light to pass through the mask. For example, the transition portion can switch between lower degrees of opacity **3000** to higher degrees of opacity **3002**. In this illustrative embodiment, the mask contains photochromic chromophores within a polymer matrix **3004**. Although initially substantially colorless, when the photochromic chromophores are allowed to freely rotate and are further exposed to certain activating wavelengths of light, the molecules will rotate into a conformation that absorbs some amount of visible light. However, when the activating light source is removed, the molecules will relax and return to a substantially colorless state. It is particularly advantageous to lock these molecules into one state or another, to prolong the visible light blocking aspect of the molecules. Further, it is advantageous to be able to controllably switch the chromophores between a locked colorless

state, wherein visible light can be freely transmitted, to a locked state that absorbs visible light and back again.

In certain embodiments, the free rotation of the photochromic chromophores can be prevented by using particular mask materials such as a photochromic polymer, wherein photochromic chromophores are contained within a polymer matrix. To further control the rotation of the photochromic chromophores, such a polymer matrix can have a controlled glass transition temperature (Tg), such that when heat is applied to the polymer matrix, the matrix undergoes a glass transition from a brittle to a more molten or rubber-like state. While in the more brittle state, the polymer matrix prevents free rotation of the photochromic chromophore, locking the photochromic chromophore into a colorless or a light-absorbing state. However, when in the less brittle, more molten state, the polymer matrix allows free rotation of the photochromic chromophore between colorless or light-absorbing states. Consequently, in this embodiment, a mask can be configured to switch between a state with one degree of opacity to a state with another degree of opacity, through the simple application of heat and activating light.

FIG. **7** is a flowchart illustrating an embodiment of a method for controlling the opacity of a photochromic polymer mask configured to switch between different levels of opacity. At step **4000**, a switchable mask implanted in the eye is exposed to both heat and an activating light source. The exposure to heat causes the polymer matrix to undergo a glass transition while the light activation of the photochromic chromophores causes the molecules to rotate and absorb visible light, causing the transition portion on the mask to become more opaque **4002**. In step **4004**, the heat source is removed and the polymer matrix undergoes a glass transition back to a more brittle form, thus locking in the light-absorbing photochromic chromophores so that they can no longer rotate, resulting in retention of the enhanced opacity of the transition portion. In step **4006**, the activating light source is removed; however the mask remains opaque because the energy-activated photochromic chromophores are not able to freely rotate back into a relaxed colorless state. In optional step **4008**, heat is again applied to the mask, causing the polymer matrix to again undergo a glass transition. This glass transition allows the photochromic chromophores to freely rotate back into their relaxed, colorless state, causing the mask to become less opaque. In optional step **4010**, the heat source is removed from the mask and the polymer matrix undergoes a glass transition back to a more brittle state, locking the photochromic chromophores into a non-rotatable state. Thus, in this example, the mask has been switched from a state with one degree of opacity to a state with another degree of opacity and back again, by the application of heat and activating light.

In some embodiments, a mask configured to controllably switch between different levels of opacity is advantageous because it can allow treatment providers to inspect the back of the eye without requiring the removal of the mask. Further, in certain embodiments, such a feature can allow for switchable changes in mask geometry from outside the eye, potentially allowing for the adjustment of the masks from a first opacity to a second different opacity for various treatments or performance objectives.

In some embodiments, the transition portion of the mask can comprise any proportion of the total mask, ranging from above 0% to 100% of the mask. For example, the transition portion can be at least about 1%, at least about 5%, at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 90%, or about 100% of the total area of the opaque portion of the mask.

In certain embodiments, the transition portion can switch between a first level of opacity that blocks the transmittance of substantially all light and a second level of opacity where substantially all light can pass through the mask. In some embodiments, the mask can be configured to switch between any level of opacity ranging from above 0 to 100%, corresponding to blocking between 0% to 100% of visible light, respectively. For example, the change in the level of opacity between the first level and the second level can be at least about 5%, at least about 10%, at least about 15%, at least about 20%, at least about 30%, at least about 40%, at least about 50%, at least about 60%, at least about 70%, at least about 80%, or more.

FIGS. **8**A-**8**F depict embodiments of various geometric configurations for the transition portion of the mask. For example, the switchable portion of the mask can switch between a uniform high transmission **5000** (FIG. **8**A) and another degree of opacity via switching of a portion of the mask such as in the top half **5002** (FIG. **8**B) or an inner annulus **5004** (FIG. **8**C), or the entire mask such as in **5006** (FIG. **8**D) and **5008** (FIG. **8**E). In further embodiments, multiple transition portions are configured to switch between various levels of opacity **5010** (FIG. **8**F).

For example, referring to FIG. **8**F, a mask **5010** having a central aperture **5012** is illustrated. A first annular zone **5014** surrounds the aperture **5012**. A second annular zone **5016** surrounds the first annular zone **5014**. A third annular zone (not illustrated) may surround the second annular zone **5016**. Each of the annular zones may comprise a homogeneous optical transmission characteristic, or may comprise an annular ring of two or more alternating or intermittent sections having distinct absorption characteristics.

In one implementation of the invention, the outer annular ring **5016** comprises a fixed opacity. The inner ring **5014** comprises a transition portion as described elsewhere herein. The opacity of the transition portion may be adjusted between a first opacity that is relatively high, such as substantially equivalent to the opacity of the outer zone **5016**, and a reduced opacity as described elsewhere herein. In effect, the invention enables the provision of a mask **5010** having an aperture **5012** of a first diameter. Adjustment of the opacity of the inner ring **5014** from a relatively high opacity to a relatively low opacity has the effect of increasing the diameter of the central aperture **5012**. This may be desirable for altering the optical characteristics of the mask, or for increasing the visual access to the interior of the eye for diagnostic or therapeutic purposes.

Alternatively, the relationship between the fixed ring and the variable ring may be reversed. Thus, the inner ring **5014** may be provided with a permanent opacity. The outer ring **5016** may be provided with a variable characteristic such that the opacity may be changed between a relatively low level and a relatively high level.

In general, the mask of the present invention may be provided on an intraocular lens, a corneal inlay, or elsewhere along the optical path. It may be provided with at least a first region having a predetermined transmission characteristic, and at least a second region having a controllable variable transmission characteristic.

The variable opacity characteristic can be accomplished by any of a variety of systems in which a change in opacity may be accomplished in response to exposure to an external stimulus. The external stimulus can be ultraviolet, visible or infrared light, heat, a radiofrequency or magnetic field, electrical

current, mechanical vibration (e.g. ultrasound) or other triggering signal that can be applied to the eye. Certain chemical systems which respond to an exposure to light will be described further herein.

As described above, in some embodiments, the mask contains at least one transition portion with photochromic chromophores contained within a polymer matrix. In a preferred embodiment, the photochromic chromophore is spiropyran, although other photochromic chromophores can be used. For example, any photochromic chromophore that undergoes a stereochemical conformational change that can be locked within a polymer matrix can be used. In certain embodiments, the photochromic chromophore or other compound can be any suitable molecule or compound that can be bound into a polymer chain. Further suitable chromophores include, but are not limited to: naphthopyrans, chromenes, fulgides, similar molecules, and mixtures thereof. In other embodiments, dimers of the photochromic chromophore can be used such as, for example, a spiropyran dimer. Desirably, in embodiments, the photochromic chromophore or compound is one that can easily rearrange in the photochromic polymer to alter the transmission state when exposed to suitable irradiation and heat, but which is more difficult to rearrange in the photochromic polymer to alter the transmission state when heat is removed. For example, further details concerning the use of photochromic chromophores within a polymer matrix can be found in U.S. Pat. No. 8,216,765, entitled "REIMAGEABLE AND REUSABLE MEDIUM AND METHOD OF PRODUCING AND USING THE REIMAGEABLE AND REUSABLE MEDIUM," filed Mar. 9, 2009. and which is hereby incorporated by reference in its entirety.

In certain embodiments, the photochromic chromophore concentration within the polymer matrix of the transition portion can be varied to result in a range of switchable opacities. For example, the concentration of photochromic chromophore can be varied to produce a switchable level of opacity within the transition portion having a change in transmission of at least about 5%, at least about 10%, at least about 20%, at least about 30%, at least about 40%, at least 50%, at least about 60%, at least about 70%, or more between the high transmission and low transmission states.

In some embodiments, the photochromic chromophore can be distributed homogenously throughout the transition portions of the mask, resulting in a constant level of opacity across the transition portions of the mask. In certain embodiments, the photochromic chromophore can be distributed heterogeneously throughout the transition portions of the mask, resulting in a non-constant level of opacity across the transition portions of the mask.

In some embodiments, the wavelength of light used to activate the photochromic chromophore to switch from a colorless or high transmission state to an opaque or relatively lower transmission state can be any wavelength of light capable of triggering an absorption transition. In certain embodiments, the wavelength of light used to activate the photochromic chromophore to switch from a colorless state to an opaque state is in the ultraviolet range. In further embodiments, the wavelength of light used to activate the photochromic chromophore is in the infrared range. In additional embodiments, the wavelength of light used to activate the photochromic chromophores is in the visible light range.

In certain embodiments, the photochromic chromophore contained within the transition portion of the mask can be selected so as to allow for exposure to selected events such as illumination and imaging via a camera without activating the photochromic chromophore. For example, the wavelength of light used by the camera to illuminate and image the mask can be of such a different wavelength of light from the activating wavelength of the photochromic chromophore that the light from the camera will not activate the photochromic chromophore. In some embodiments, near infrared light could be used by the camera, while ultraviolet light is used for the photochromic chromophore.

In certain embodiments, the wavelength of energy used by the illuminating and imaging camera is the same as the wavelength of energy used to heat the system. In some embodiments, the wavelength of energy used by the camera is different from the wavelength of energy used to heat the system.

As described above, in some embodiments, the transition portions of the mask contain light-activated photochromic chromophores contained within a polymer matrix with a controlled Tg. In some embodiments, the photochromic chromophore is polymerized directly into the backbone of the polymer used in the polymer matrix. Suitable photochromic chromophores are described above, however, in some embodiments suitable polymers can be formed from first and second monomers. For example, further details concerning the formation of first and second monomers and incorporation of a photochromic chromophore into a polymer matrix can be found in U.S. Pat. No. 8,216,765, entitled "REIMAGEABLE AND REUSABLE MEDIUM AND METHOD OF PRODUCING AND USING THE REIMAGEABLE AND REUSABLE MEDIUM," filed Mar. 9, 2009 and which was incorporated by reference above. FIG. **9** illustrates one embodiment of a synthesis scheme for a photochromic monomer. FIG. **10** illustrates one embodiment of a synthesis scheme for the synthesis of a photochromic polymer from the co-polymerization of a photochromic monomer.

In certain embodiments, the photochromic polymer is optionally dissolved or dispersed in any suitable carrier, such as a solvent, a polymer binder, or the like. Water may be used as a solvent for water soluble photochromic polymers and water-soluble binders such as poly(vinyl alcohol) and poly (acrylic acid). Other suitable solvents include, for example, straight chain aliphatic hydrocarbons, branched chain aliphatic hydrocarbons, and the like, such as where the straight or branched chain aliphatic hydrocarbons have from about 1 to about 30 carbon atoms. For example, a non-polar liquid of the ISOPAR™ series (manufactured by the Exxon Corporation) may be used as the solvent. These hydrocarbon liquids are considered narrow portions of iso-paraffinic hydrocarbon fractions. Other suitable solvent materials include, for example, the NORPAR™ series of liquids, which are compositions of n-paraffins available from Exxon Corporation, the SOLTROL™ series of liquids available from the Phillips Petroleum Company, and the SHELLSOL™ series of liquids available from the Shell Oil Company. Mixtures of one or more solvents, i.e., a solvent system, can also be used, if desired. In addition, more polar solvents can also be used, if desired. Examples of more polar solvents that may be used include halogenated and nonhalogenated solvents, such as tetrahydrofuran, trichloro- and tetrachloroethane, dichloromethane, chloroform, monochlorobenzene, toluene, xylenes, acetone, methanol, ethanol, xylenes, benzene, ethyl acetate, dimethylformamide, cyclohexanone, N-methyl acetamide and the like. The solvent may be composed of one, two, three or more different solvents. When two or more different solvents are present, each solvent may be present in an equal or unequal amount by weight ranging for example from about 5% to 90%, particularly from about 30% to about 50%, based on the weight of all solvents.

In some embodiments, the photochromic polymer can be dispersed in another, non-photochromic polymer binder. Such an additional polymer binder may be desired, for

example, depending on the properties, characteristics, and the like of the photochromic polymer. Of course, it will be understood that an additional polymer binder may not be required in some embodiments, as the photochromic polymer can itself function as a binder material. Suitable examples of polymer binders that can be used include, but are not limited to, polyalkylacrylates like polymethyl methacrylate (PMMA), polycarbonates, polyethylenes, oxidized polyethylene, polypropylene, polyisobutylene, polystyrenes, poly (styrene)-co-(ethylene), polysulfones, polyethersulfones, polyarylsulfones, polyarylethers, polyolefins, polyacrylates, polyvinyl derivatives, cellulose derivatives, polyurethanes, polyamides, polyimides, polyesters, silicone resins, epoxy resins, polyvinyl alcohol, polyacrylic acid, and the like. Copolymer materials such as polystyrene-acrylonitrile, polyethylene-acrylate, vinylidenechloride-vinylchloride, vinylacetate-vinylidene chloride, styrene-alkyd resins are also examples of suitable binder materials. The copolymers may be block, random, or alternating copolymers. In some embodiments, polymethyl methacrylate or a polystyrene is the polymer binder, in terms of their cost and wide availability. The polymer binder, when used, has the role to provide a coating or film forming composition.

Phase change materials can also be used as the polymer binder. Phase change materials are known in the art, and include for example crystalline polyethylenes such as Polywax® 2000, Polywax® 1000, Polywax® 500, and the like from Baker Petrolite, Inc.; oxidized wax such as X-2073 and Mekon wax, from Baker-Hughes Inc.; crystalline polyethylene copolymers such as ethylene/vinyl acetate copolymers, ethylene/vinyl alcohol copolymers, ethylene/acrylic acid copolymers, ethylene/methacrylic acid copolymers, ethylene/carbon monoxide copolymers, polyethylene-b-polyalkylene glycol wherein the alkylene portion can be ethylene, propylene, butylenes, pentylene or the like, and including the polyethylene-b-(polyethylene glycol)s and the like; crystalline polyamides; polyester amides; polyvinyl butyral; polyacrylonitrile; polyvinyl chloride; polyvinyl alcohol hydrolyzed; polyacetal; crystalline poly(ethylene glycol); poly (ethylene oxide); poly(ethylene therephthalate); poly (ethylene succinate); crystalline cellulose polymers; fatty alcohols; ethoxylated fatty alcohols; and the like, and mixtures thereof.

In some embodiments, any suitable polymer that has one or more photochromic molecules or compounds bound to the polymer backbone, can be used. Such photochromic polymers can have the photochromic molecules or compounds covalently bound to the polymer backbone within the polymer chain itself. Such groups can be introduced into the polymer chain, for example, by including the photochromic molecules or compounds during the polymer preparation process, such as in the form of reactive units, monomer units, or the like, or they can be added to an already formed non-photochromic polymer material through known chemical functionalization reactions.

Where multiple photochromic molecules or compounds are present in the polymer chain, the multiple photochromic molecules or compounds can be the same or different. Likewise, the photochromic polymer can include only one type of photochromic polymer, or can include a mixture of two or more different types of photochromic polymer (such as different photochromic polymers having different photochromic molecules or compounds in the polymer chain, or the same or different photochromic molecules or compounds in different polymer chains. Because the photochromic polymer is converted between its colored and colorless states by the use of light and heat, the polymer and photochromic molecules or compounds are desirably selected such that the photochromic polymer has thermal properties that can withstand the elevated temperatures that may be used.

FIG. **11** depicts an embodiment of a suitable incorporation of a photochromic chromophore into a polymer backbone. In this illustrative embodiment, the photochromic chromophore can be between a first and second monomer. Likewise, any suitable non-photochromic polymer materials may be selected for forming the non-photochromic parts of the photochromic polymer. Examples include, but are not limited to, the polymers described above as useful for a polymer binder. For example, in one embodiment, suitable polymers include those that can be formed from first and second monomers. The first monomer may be diacyl chlorides, diacids, its dimethyl esters, or its unhydrous cyclic esters such as oxalyl, malonyl, succinyl, glutaryl, adipoyl, pimeloyl, suberoyl, azelaoyl, sebacoyl, fumaryl, terephthalic, isophthalic, phthalic, and mixtures thereof, wherein the alkyl portion can be a straight, branched or cyclic, saturated or unsaturated, substituted or unsubstituted, from 1 to about 40 carbon atoms, a substituted or unsubstituted aromatic or heteroaromatic group. The second monomer may be bisphenols or diols such as Bis-phenol A, bisphenol B, bisphenol C, bisphenol F, bisphenol M, bisphenol P, bisphenol AP, bisphenol Z, ethylene glycol, propylene glycol, butylene glycol, pentylene glycol, hexylene glycol, heptylene glycoldiethylene glycol, dipropylene glycol, dipropylene glycol, cyclohexyldimethanol, bisphenol A ethoxylate, bisphenol A propoxylate, and mixtures thereof, wherein the alkyl portion can be a straight, branched or cyclic, saturated or unsaturated, substituted or unsubstituted, from 1 to about 40 carbon atoms, an substituted or unsubstituted aromatic or heteroaromatic group.

In certain embodiments, a photochromic polymer containing a photochromic chromophore within a polymer backbone is mixed with a second miscible polymer with side-chain crystallizable side groups such as polyoctadecyl acrylate. For example, further details concerning side-chain crystallizable polymers can be found in U.S. Pat. No. 4,830,855, entitled "TEMPERATURE-CONTROLLED ACTIVE AGENT DISPENSER," filed Nov. 13, 1987 and which is hereby incorporated by reference in its entirety. In certain embodiments, the photochromic chromophore can be polymerized directly into side-chain crystallizable polymers. In certain embodiments, the first and/or second monomers described above can be side-chain crystallizable polymers.

FIG. **12** depicts an embodiment of a side-chain crystallizable polymer, where X is a first monomer unit, Y is a second monomer unit, Z is a backbone atom, S is a spacer unit and C is a crystallizable group. Side-chain crystallizable polymers, sometimes called "comb-like" polymers are well known and available commercially. These polymers are reviewed in J. Poly. Sci.: Macromol. Rev. (1974) 8: 117-253. In some embodiments the molecular weight of C is equal to or greater than twice the sum of the molecular weights of X, Y and Z. These polymers have a heat of fusion (—Ht) of at least about 5 calories/g, preferably at least about 10 calories/g. The backbone of the polymer (defined by X, Y and Z) may be any organic structure (aliphatic or aromatic hydrocarbon, ester, ether, amide, etc.) or an inorganic structure (sulfide, phosphazine, silicone, etc.). The spacer linkages can be any suitable organic or inorganic unit, for example ester, amide, hydrocarbon, phenyl, ether, or ionic salt (for example a carboxyl-alkyl ammonium or sulphonium or phosphonium ion pair or other known ionic salt pair). The side-chain (defined by S and C) may be aliphatic or aromatic or a combination of aliphatic and aromatic, but must be capable of entering into a crystalline state. Common examples are linear aliphatic side-chains of at

least 10 carbon atoms, fluorinated aliphatic side-chains of at least 6 carbons, and p-alkyl styrene side-chains wherein the alkyl is of 8 to 24 carbon atoms.

In some embodiments, the length of the side-chain moiety is usually greater than 5 times the distance between side-chains in the case of acrylates, methacrylates, vinyl esters, acrylamides, methacrylamides, vinyl ethers and alpha olefins. In certain embodiments, a fluoroacrylate alternate copolymer with butadiene as the side-chain can be as little as 2 times the length as the distance between branches. In some embodiments, the side-chain units should make up greater than 50% of the volume of the polymer, preferably greater than 65% of the volume. Co-monomers added to a side-chain polymer usually have an adverse effect on crystallinity. Small amounts of various co-monomers can be tolerated, usually up to 10 to 25 volume percent. In some embodiments, it is desirable to add small amounts of co-monomer, for example cure site monomers such as acrylic acid, glycidal methacrylate, maleic anhydride, amino function monomer and the like. Specific examples of side-chain crystallizable monomers are the acrylate, fluoroacrylate, methacrylate and vinyl ester polymers described in J. Poly. Sci. (1972) 10:50 3347; J. Poly. Sci. (1972) 10: 1657; J. Poly. Sci. (1971) 9:3367; J. Poly. Sci. (1971) 9: 3349; J. Poly. Sci. (1971) 9:1835; J.A.C.S. (1954) 76: 6280; J. Poly. Sci. (1969) 7: 3053; Polymer J. (1985) 17: 991. corresponding acrylamides, substituted acrylamide and maleimide polymers (J. Poly. Sci., Poly. Physics Ed. (1980) 18: 2197; polyalphaolefin polymers such as those described in J. Poly. Sci.: Macromol. Rev. (1974) 8: 117-253 and Macromolecules (1980) 13: 12, polyalkylvinylethers, polyalkylethylene oxides such as those described in Macromolecules (1980) 13: 15, alkylphosphazene polymers, polyamino acids such as those described in Poly. Sci. USSR (1979) 21: 241, Macromolecules (1985) 18: 2141, polyisocyanates such as those described in Macromolecules (1979) 12: 94. polyurethanes made by reacting amine- or alcohol-containing monomers with long chain alkyl isocyanates, polyesters and poly ethers. Polysiloxanes and polysilanes such as those described in Macromolecules (1986) 19: 611 and p-alkylstyrene polymers such as those described in J.A.C.S. (1953) 75: 3326 and J. Poly. Sci. (1962) 60: 19.

In certain embodiments, the photochromic chromophore can be incorporated into a polyester polycondensate. For example, further details concerning this type of incorporation can be found in U.S. Pat. No. 3,918,972, entitled "IMAGING PROCESS UTILIZING A POLYESTER POLYCONDENSATE CONTAINING SPIROPYRAN PHOTOCHROMIC GROUPS" filed Aug. 13, 1973 and hereby incorporated by reference in its entirety. Further details concerning additional photochromic polycondensates can be found in U.S. Pat. No. 4,026,869 entitled PHOTOCHROMIC POLYCONDENSATES, filed Jul. 21, 1975 and hereby incorporated by reference in its entirety.

In some embodiments, linear polycondensates of the polyester type are provided characterized in that they contain spiropyran photochromic groups as an integral part of the main polymer chain. In certain embodiments, they can be prepared by polycondensation of Bisphenol-A and a photochromic compound carrying a hydroxyalkyl group on either side of the photochromic moiety, with a dicarboxylic acid of the saturated dicarboxylic acid series, preferably with succinic acid, adipic acid, glutaric acid and pimelic acid. In this process the dicarboxylic acid in the form of a diacid dichloride is dissolved in an organic liquid, such as methylene chloride, dichloroethane, tetrachloroethane, benzene or toluene, which is also a solvent for the copolycondensate to be formed. The bisphenol is dissolved in another liquid, which is immiscible with the above organic liquid. Preferably water is used as a solvent for the bisphenol and an equivalent amount of a metal hydroxide, such as sodium hydroxide or potassium hydroxide is added to the water in order to form immediately the corresponding diphenolate. The reaction speed is greatly increased by using quaternary ammonium compounds as catalysts. The two solutions are mixed and stirred vigorously at the reaction temperature, whereby the copolyester is formed in solution. In the same way the photochromic copoly-condensates of the invention are formed. In some embodiments, a photochromic compound carrying on either side of the photochromic moiety an hydroxyalkylgroup is made to react with an excess of the diacid dichloride e.g. of succinic acid, adipic acid, glutaric acid, or pimelic acid, and the photochrome-bis-acid chloride formed in this way is made to react in a two-phase reaction mixture with a diphenolate of bisphenol-A. Suitable photochromic compounds carrying two hydroxyalkyl groups on either side of the photochromic moiety are compounds, containing spiropyran groups.

In certain embodiments, the photochromic chromophore is directly polymerized into a polymer backbone as described above and mixed with the miscible polymer combination described above. In some embodiments, the photochromic dye is directly polymerized into the polymer backbone of a polymer that also has side chain crystallizable side groups such as described above. In certain embodiments, the photochromic oligomers or monomers described above and in U.S. Pat. No. 8,216,765 can be mixed with the aforementioned miscible combination of polymers. In some embodiments, a dimer of any of the aforementioned photochromic chromophores can be mixed with any of the aforementioned polymers.

In further embodiments, the Tg of the polymer matrix can be between 30°-150° C. For example, the Tg can be at least about 30° C., about 35° C., about 40° C., about 45° C., about 50° C., about 55° C., about 60° C., about 65° C., about 70° C., about 75° C., about 80° C., about 85° C., about 90° C., about 95° C., about 100° C., about 105° C., about 110° C., about 115° C., about 120° C., about 125° C., about 130° C., about 135° C., about 140° C., about 145° C., or about 150° C.

The Tg of the polymer matrix can be varied by changing the chemical properties of the polymers comprising the polymer matrix. In some embodiments, the Tg of the polymer matrix can be modified by varying the chain length of the monomer used in polymerization. In further embodiments, the Tg is controlled by varying the chain length of the side groups that branch from the polymer backbone. In other embodiments, the Tg of the polymer matrix can be adjusted by varying the spacing between the side-chains. In certain embodiments, the Tg of the polymer is controlled by varying the cross-link density of the polymer. In other embodiments, the Tg of the polymer can be controlled by varying the molecular weight of the polymer. Any of the aforementioned polymer properties can be adjusted together or separately to tune the Tg of the polymer matrix.

As described previously, in some embodiments, heat can be used to cause the polymer matrix to undergo a glass transition. In certain embodiments, heat is provided to the polymer matrix via focused radiant energy from outside the eye. For example, this focused radiant energy can be a laser. In some embodiments, ultrasonic energy can be applied to the mask to heat it. In some embodiments, heat or other initiator is applied to the transition portions, or to one of multiple transition portions of the mask.

In some embodiments, an axicon lens can be used to focus a circular beam of radiant energy into the eye and onto a mask

to heat an annular area of the mask inside the eye. In certain embodiments, the annular pattern created by the axicon lens can be focused further before entering the eye to create a confocal focusing of the annular pattern to bring it to a smaller, higher energy density annular region of focus inside the eye on the mask. In certain embodiments, a biconvex toric lens could be used to achieve the confocal focusing of the annular pattern output from the axicon lens element to focus it confocally into the eye. In some embodiments, other optical configurations instead of an axicon lens can be used to provide a confocally focused annular beam of energy into the eye.

In some embodiments, focusing of the radiant energy into the eye and onto the mask would be completed with simultaneous microscope viewing for better control and monitoring of the procedure inside the eye. This arrangement is advantageous, as the focus of the radiation area on the mask and the change of the photochromic chromophores in this area could be directly observed.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or process illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others. The scope of the inventions is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An ophthalmic device comprising:

a mask configured to transmit substantially all visible light along an optical axis of the eye;

the mask further comprising a transition portion configured to switch between a first degree of opacity and a second degree of opacity in response to application of an external stimuli;

wherein the transition portion is configured to remain locked into the second degree of opacity after removal of the external stimuli until another application of the external stimuli, the transition portion then returning to the first degree of opacity; and

wherein the transition portion comprises a photochromic chromophore within a polymer matrix.

2. The ophthalmic device of claim **1**, wherein the mask further comprises an aperture configured to transmit substantially all visible light along the optical axis of the eye.

3. The ophthalmic device of claim **1**, wherein the mask further comprises a plurality of holes extending at least partially between an anterior surface of the mask and a posterior surface of the mask.

4. The ophthalmic device of claim **1**, further comprising an intraocular lens coupled with the mask.

5. The ophthalmic device of claim **1**, wherein the second degree of opacity allows transmission of substantially all visible light through the transition portion of the mask.

6. The ophthalmic device of claim **1**, wherein the first degree of opacity prevents transmission of substantially all visible light through the transition portion of the mask.

7. The ophthalmic device of claim **1**, wherein the transition portion of the mask comprises at least 50% of the total mask.

8. The ophthalmic device of claim **1**, wherein the photochromic chromophore is spiropyran.

9. The ophthalmic device of claim **1**, wherein the transition portion is configured to switch between a first degree of opacity and a second degree of opacity via application of both light and heat.

10. The ophthalmic device of claim **1**, wherein the polymer matrix has a glass transition temperature of between 30-150° C.

11. The ophthalmic device of claim **1**, wherein the external stimuli is chosen from the group consisting of light, heat, and electrical current.

12. The ophthalmic device of claim **1**, wherein the external stimuli comprises heat provided by a laser.

13. The ophthalmic device of claim **1**, wherein the external stimuli comprises a combination of light and heat.

14. The ophthalmic device of claim **1**, wherein the glass transition temperature of the polymer matrix is approximately 50° C.

15. The ophthalmic device of claim **1**, wherein the polymer matrix comprises a side-chain crystallizable polymer.

16. The ophthalmic device of claim **1**, wherein the mask is configured to switch between the first degree of opacity, the second degree of opacity, and a third degree of opacity in response to an external stimuli.

17. The ophthalmic device of claim **1**, wherein the transition portion is further configured to remain locked into the first degree of opacity until application of the external stimuli.

18. The ophthalmic device of claim **1**, wherein the polymer matrix comprises polymethyl methacrylate.

19. An intraocular mask, comprising:

a photochromic chromophore within a polymer matrix, the photochromic chromophore configured to rotate between a first state wherein the intraocular mask comprises a first degree of opacity and a second state wherein the intraocular mask comprises a second degree of opacity, the photochromic chromophore configured to rotate only when the polymer matrix has passed through a glass transition from a brittle state into a molten state in response to application of an external stimuli, the polymer matrix configured to return to the brittle state upon removal of the external stimuli and remain locked in the brittle state until another application of the external stimuli.

20. The intraocular mask of claim **19**, wherein the photochromic chromophore is substantially opaque while in the first state.

21. The intraocular mask of claim **20**, wherein the photochromic chromophore is substantially colorless while in the second state.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,204,962 B2
APPLICATION NO. : 13/802340
DATED : December 8, 2015
INVENTOR(S) : Thomas A. Silvestrini

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page

In column 2 (page 1, item 56) at line 16, Under Other Publications, change "Accomodation" to --Accommodation--.

In column 2 (page 7, item 56) at line 44, Under Other Publications, change "Opthalmology" to --Ophthalmology--.

In column 2 (page 7, item 56) at line 45, Under Other Publications, change "Accomodation" to --Accommodation--.

In column 1 (page 8, item 56) at line 29, Under Other Publications, change "accomodation." to --accommodation.--.

In column 1 (page 8, item 56) at line 52, Under Other Publications, change "Hydrophopic" to --Hydrophobic--.

In column 1 (page 8, item 56) at line 53, Under Other Publications, change "Light-Absorving" to --Light-Absorbing--.

In column 1 (page 8, item 56) at line 60, Under Other Publications, change "Hydrophopic" to --Hydrophobic--.

In column 1 (page 8, item 56) at line 60, Under Other Publications, change "Absorving" to --Absorbing--.

In column 2 (page 8, item 56) at line 27, Under Other Publications, change "Opthalmology," to --Ophthalmology,--.

In column 2 (page 8, item 56) at line 59, Under Other Publications, change "Opthalmology," to --Ophthalmology,--.

In column 1 (page 9, item 56) at line 34, Under Other Publications, change "flouride" to --fluoride--.

Signed and Sealed this
Fifth Day of July, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office

In column 1 (page 9, item 56) at line 60, Under Other Publications, change "Opthalmology," to --Ophthalmology,--.

In column 2 (page 9, item 56) at line 5, Under Other Publications, change "Opthalmology," to --Ophthalmology,--.

In column 2 (page 9, item 56) at line 48, Under Other Publications, change "Manfacturing" to --Manufacturing--.

In column 2 (page 9, item 56) at line 56, Under Other Publications, change "prosepective" to --prospective--.

In column 1 (page 10, item 56) at line 4, Under Other Publications, change "Opthalmology," to --Ophthalmology,--.

In column 2 (page 10, item 56) at line 7, Under Other Publications, change "Keratoplosty:" to --Keratoplasty:--.

In column 2 (page 10, item 56) at lines 7-8, Under Other Publications, change "Cyropreservation,"" to --Cryopreservation,"--.

In the specification

In column 4 at line 54, Change "2034 a,b" to --2034a,b--.

In column 4 at line 55, Change "co-polymers," to --copolymers,--.

In column 11 at line 30, Change "2009." to --2009,--.

In column 13 at line 40, Change "therephthalate);" to --terephthalate);--.

In column 14 at line 15, Change "unhydrous" to --anhydrous--.

In column 14 at line 55, Change "(—Ht)" to --(~Ht)--.